Injection moulding- A novel method of solid oral dosage form manufacturing

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Introduction:

The most preferred route of drug administration is orally using tablets however when administering BCS Class II drugs current technologies can be limited. Injection Moulding is a technique to produce solid oral dosage forms and can combine drug with polymers increasing drug dissolution due to the drug-polymer interactions and stabilisation of the amorphous form. (1) However using polymers on their own often leads to sustained release so additional excipients are required to produce immediate release dosage forms.

Methods:

Dosage forms were produced using HAAKE Minijet Pro Injection Moulder, ThermoScientific. The formulations chosen were pre-extruded by the 11mm Hot Melt Extruder, ThermoScientific. Pressure studies were carried out using 3200C Arburg All-rounder Injection Moulder. Analysis carried out: HPLC, XRD, DSC and Dissolution testing.

Results:

High drug doses can be achieved using IM however when the ratio of drug to polymer reaches 50:50 some stability issues occur as the amorphous drug recrystallizes. From a selection of disintegrating agents analysed, one compound showed the most potential for disintegration and dissolution capabilities. However, sustained released was still observed. The pressure study showed that pressure is lost in the system.

Conclusion:

The dissolution results show that in order to obtain a more immediate release the concentration of disintegrating requires further exploration. However, a varied range of high drug doses can be achieved using Injection Moulding.

Keywords: drug doses; injection moulding; recrystallization

References

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